

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

JC966 U.S. PTO
09/800855
03/07/01



Applicants: Stephen T. Sonis and Edward G. Fey

Serial No.: Continuation of 09/265,299 Art Unit: Not Yet Assigned

Filed: March 7, 2001 Examiner: Not Yet Assigned

For: *METHODS AND COMPOSITIONS FOR TREATING AND PREVENTING MUCOSITIS*

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including six (6) pages of Form PTO-1449. The documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/265,299, filed March 9, 1999, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 01-2507.

Continuation of U.S.S.N. 09/265,299
Filed: March 7, 2001
Information Disclosure Statement
Express Mail Label No. EL 709 420 295 US
Date of Deposit: March 7, 2001

U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
4,666,897	05-19-1987	Golub, et al.	514/152
5,190,917	03-02-1993	Lezdey, et al.	514/12
5,192,780	03-09-1993	York, et al.	514/357
5,215,965	06-01-1993	Lezdey, et al.	514/12
5,230,895	06-27-1993	Czarnecki, et al.	424/422
5,310,545	05-10-1993	Eisen	424/49
5,385,941	01-31-1995	Fawzi, et al.	514/567
5,512,055	04-30-1996	Domb, et al.	604/265
5,578,315	11-26-1996	Chien, et al.	424/435
5,654,312	09-05-1997	Andrulis, Jr., et al.	514/279
5,674,708	10-07-1997	Cooperman, et al.	435/69.2
5,707,653	01-13-1998	Goldberg	424/464
5,788,982	08-04-1998	Nadoolman, et al.	424/440
5,824,297	10-20-1998	Iwata, et al.	424/85.1
5,846,525	12-08-1998	Maniar, et al.	424/78.12

Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
7069851 A	03-14-1995	Lion Corp.	JP (Abstract)
8268854 A	10-15-1996	Sunstar KK	JP (Abstract)
0 355 067 A1	02-12-1990	Celltech Ltd.	EP
WO 95/17154 A2	06-29-1995	Andrulis Pharmaceutical Corporation	PCT
WO 97/09973 A2	03-20-1997	The Regents of the University of California	PCT

Publications

AMIN, et al., "A novel mechanism of action of tetracyclines: effects on nitric oxide synthases," *Proc Natl Acad Sci U S A.* 93(24):14014-9 (1996).

AMON, et al., "CGP 41251, a novel protein kinase inhibitor with in vitro selectivity for protein kinase C, strongly inhibits immunological activation of human skin mast cells and human basophils," *Pharmacology.* 47(3):200-8 (1993).

ARMITAGE, et al., "Microscopic evaluation of clinical measurements of connective tissue attachment levels," *Journal of Clinical Periodontology* 4:173-190 (1977).

Continuation of U.S.S.N. 09/265,299
Filed: March 7, 2001
Information Disclosure Statement
Express Mail Label No. EL 709 420 295 US
Date of Deposit: March 7, 2001

BACH, et al., "Experiments on the mode of action of piriprost (U-60,257), an inhibitor of leukotriene formation in cloned mouse mast cells and in rat basophil leukemia cells," *Biochem Pharmacol.* 36(9):1461-6 (1987).

BADGER, et al., "Pharmacological profile of SB 203580, a selective inhibitor of cytokine suppressive binding protein/p38 kinase, in animal models of arthritis, bone resorption, endotoxin shock and immune function," *J Pharmacol Exp Ther.* 279(3):1453-61 (1996).

BALLA, et al., "Tissue responses to furcation perforations repaired with various dental materials," *Journal of Dental Research* 68:1144 (1989).

BAUDITZ, et al., "Treatment with tumour necrosis factor inhibitor oxpentifylline does not improve corticosteroid dependent chronic active Crohn's disease," *Gut.* 40(4):470-4 (1997).

BONDI, et al., "Local antimicrobial therapy of oral mucositis in Paediatric patients undergoing bone marrow transplant," *Oral Oncology* 33:322-326 (1997).

CAUGHEY, et al., "Bis(5-amidino-2-benzimidazolyl)methane and related amidines are potent, reversible inhibitors of mast cell tryptases," *J Pharmacol Exp Ther.* 264(2):676-82 (1993).

CZARNETZKI, et al., "Topical tiacrilast, a potent mast cell degranulation inhibitor, does not improve adult atopic eczema," *Dermatology* 187:112-114 (1993).

DE PAULIS, et al., "FK-506, a potent novel inhibitor of the release of proinflammatory mediators from human Fc epsilon RI+ cells," *J Immunol.* 146(7):2374-81 (1991).

FEWTRELL & GOMPERTS, "Quercetin: a novel inhibitor of Ca²⁺ influx and exocytosis in rat peritoneal mast cells," *Biochimica et Biophysica Acta* 469:52-60 (1977).

FIRARLI, et al. "Antioxidative activities of some chemotherapeutics. A possible mechanism in reducing gingival inflammation," *J Clin Periodontol.* 21(10):680-3 (1994).

GILBERTSON-BEADLING, et al., "The tetracycline analogs minocycline and doxycycline inhibit angiogenesis in vitro by a non-metalloproteinase-dependent mechanism," *Cancer Chemother Pharmacol.* 36(5):418-24 (1995).

GREENWALD, et al., "Tetracyclines suppress matrix metalloproteinase activity in adjuvant arthritis and in combination with flurbiprofen, ameliorate bone damage," *J Rheumatol.* 19(6):927-38 (1992).

HALLAHAN, et al., "Ketoconazole attenuates radiation-induction of tumor necrosis factor," *Int J Radiat Oncol Biol Phys.* 29(4):777-80 (1994).

HANAZAWA, et al., "Expression of Monocyte Chemoattractant Protein 1 (MCP-1) in Adult Periodontal Disease: Increased Monocyte Chemotactic Activity in Crevicular Fluids and Induction of MCP-1 Expression in Gingival Tissues," *Infection and Immunity* 61:5219-5224 (1993).

HANAZAWA, et al., "Functional Role of Interleukin 1 in Periodontal Disease: Induction of Interleukin 1 Production by *Bacteroides gingivalis* Lipopolysaccharide in Peritoneal Macrophages from C3H/HeN and C3H/HeH Mice," *Infection and Immunity* 50:262-270 (1985).

HANEMAAIJER, et al., "Inhibition of MMP synthesis by doxycycline and chemically modified tetracyclines (CMTs) in human endothelial cells," *Adv Dent Res.* 12(2):114-8 (1998).

HATTORI, et al., "A metalloproteinase inhibitor prevents lethal acute graft-versus-host disease in mice," *Blood*. 90(2):542-8 (1997).

HU, et al., "I-FLICE, a novel inhibitor of tumor necrosis factor receptor-1- and CD-95-induced apoptosis," *J Biol Chem.* 272(28):17255-7 (1997).

JANDINSKI, et al., "Interleukin- Beta in Crevicular Fluids During Periodontal Health and Disease," *Journal of Dental Research Abstracts* 68:1233 (1989).

JEFFCOAT, et al., "Treatment of periodontal disease in beagles with lodoxamide ethyl, an inhibitor of mast cell release," *Journal of Periodontal Research* 20:532-541 (1985).

JOHNSON, et al., "The characterization of lodoxamide, a very active inhibitor of mediator release, in animal and human models of asthma," *Agents Actions.* 18(3-4):301-5 (1986).

KAMAGATA, et al., "Cytokine Production in Human Inflamed Gingival Tissue," *Journal of Dental Research Abstracts* 68:525 (1989).

MCGEEHAN, et al., "Regulation of tumour necrosis factor-alpha processing by a metalloproteinase inhibitor," *Nature.* 370(6490):558-61 (1994).

MORIMOTO, et al., "KB-R7785, a novel matrix metalloproteinase inhibitor, exerts its antidiabetic effect by inhibiting tumor necrosis factor- production," *Life Sciences* 61:795-803 (1997).

MÜLLBERG, et al., "A metalloprotease inhibitor blocks shedding of the IL-6 receptor and the p60 TNF receptor," *J Immunol.* 155(11):5198-205 (1995).

MURAKAMI, et al., "Gabexate mesilate, a synthetic protease inhibitor, attenuates endotoxin-induced pulmonary vascular injury by inhibiting tumor necrosis factor production by monocytes," *Crit Care Med.* 24(6):1047-53 (1996).

Continuation of U.S.S.N. 09/265,299
Filed: March 7, 2001
Information Disclosure Statement
Express Mail Label No. EL 709 420 295 US
Date of Deposit: March 7, 2001

Physicians Desk Reference, 51st Edition, p. 2232, 1997.

PILLSBURY, et al., "Prostaglandin inhibitor and radiotherapy in advanced head and neck cancers," *Arch Otolaryngol Head Neck Surg.* 112(5):552-3 (1986).

PIRIE-SHEPHERD, et al., "Differential inhibition of rat mast cell proteinase I and II by members of the -1- proteinase inhibitor family of serine proteinase inhibitors," *The Journal of Biological Chemistry* 266:17314-17319 (1991).

RANNEY & MONTGOMERY, "Vascular Leakage Resulting from Topical Application of Endotoxin to the Gingiva of the Beagle Dog," *Archs Oral Biol.* 18:963-970 (1973).

RENGGLI & REGOLATI, "Intracrevicular sampling of leukocytes using plastic strips," *Helv. Odont. Acta* 16:93-99 (1972).

ROTHWELL & SPEKTOR, "Palliation of radiation-related mucositis," *Spec Care Dentist.* 10(1):21-5 (1990).

SCHENK, et al., "Controlled local delivery of tetracycline HCl in the treatment of periimplant mucosal hyperplasia and mucositis. A controlled case series," *Clin Oral Implants Res.* 8(5):427-33 (1997).

SIEGEL, et al., "The measurement of gingival fluid," *J. Periodontol.* 43:682-684 (1972).

SINGH, et al., "Capsaicin (8-methyl-N-vanillyl-6-nonenamide) is a potent inhibitor of nuclear transcription factor-kappa B activation by diverse agents," *J Immunol.* 157(10):4412-20 (1996).

SINCHOLLE, et al., "Anti-inflammatory activity of a dual inhibitor of cyclooxygenase and lipoxygenase pathways, CBS-1108 (2-acetylthiophene-2-thiazolylhydrazone)," *Arzneimittelforschung.* 35(8):1260-3 (1985).

SONIS, "Mucositis as a biological process: a new hypothesis for the development of chemotherapy-induced stomatotoxicity," *Oral Oncol.* 34(1):39-43 (1998).

TILG, et al., "Immune response modulation by pentoxifylline in vitro," *Transplantation* 56:196-201 (1993).

TRIPPLETT, et al., "SK&F 86002, a dual cytokine and eicosanoid inhibitor, attenuates endotoxin-induced cardiopulmonary dysfunction in the pig," *Shock* 6(5):357-64 (1996).

VERDI, et al., "Cancer Therapy and Oral Mucositis," *Drug Safety* 9:185-195 (1993).

Continuation of U.S.S.N. 09/265,299
Filed: March 7, 2001
Information Disclosure Statement
Express Mail Label No. EL 709 420 295 US
Date of Deposit: March 7, 2001

WALSH, et al., "Relationship between mast cell degranulation and inflammation in the oral cavity," *J Oral Pathol Med.* 24(6):266-72 (1995).

Continuation of U.S.S.N. 09/265,299
Filed: March 7, 2001
Information Disclosure Statement
Express Mail Label No. EL 709 420 295 US
Date of Deposit: March 7, 2001

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284

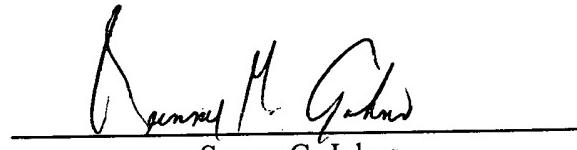
Dated: March 7, 2001

ARNALL GOLDEN & GREGORY, LLP
2800 One Atlantic Center
1201 W. Peachtree Street
Atlanta, Georgia 30309-3450
(404) 873-8794
(404) 873-8795 (fax)

Continuation of U.S.S.N. 09/265,299
Filed: March 7, 2001
Information Disclosure Statement
Express Mail Label No. EL 709 420 295 US
Date of Deposit: March 7, 2001

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that this paper and any documents referred to as attached therein are being deposited with the United States Postal Service on this date, March 7, 2001, in an envelope as "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10, Mailing Label Number EL 709 420 295 US addressed to Box Patent Application, Assistant Commissioner of Patents and Trademarks, Washington, D.C. 20231.



Sunny G. Johns

Date: March 7, 2001